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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/351,985	07/12/1999	FRIEDRICH BRAUN	A32585-PCT-U	1552

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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 04/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/351,985

Applicant(s)

BRAUN ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on December 3, 2001 & January 31, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Receipt of applicants' amendments and remarks submitted December 3, 2001 and January 31, 2002 is acknowledged.

#### *Claim Rejections 35 U.S.C. - 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1–20 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Read et al. (US 5,902,608 of record) and Patat et al. (US 5,589,462 of record) in view of Delmas (US 5,618,663 of record), Dimoudis et al. and (CA abstract, AN 1996:313895, 1996, of record) for reasons essentially the same as set forth in the prior office action. Regarding the newly added limitation that the claimed medical product further containing a thrombocyte activating stimulus selected from the group consisting of collagen, thrombin, trypsin, ADP, serotonin and andrenalin, note the amendments are not sufficient to make the claimed invention nonobvious from the references on the record. Specifically, collagen, thrombin et al. are well known physiological activators which activate platelet to release growth factor. See, column 5, line 28–31 in Delmas. Further it is known that exogenous thrombin is known to be useful together with platelet composition and thrombin coagulable protein. Particularly, immediately before the usage, adding thrombin to platelet composition is known. In fact, the feature of the composition disclosed by Patat is that it combines haemostatic and adhesive properties of concentrates of thrombin –coagulable proteins and the platelet extract. See, column 1–3, particularly, column 2,

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lines 55-59 and column 5, lines 21-30. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition comprising platelet, thrombin coagulable protein such as fibrinogen, and thrombin for wound healing.

Applicants' amendments and remarks submitted December 3, 2001 and January 21, 2002 have been fully considered, and are persuasive to overcome the rejections under 35 U.S.C. 112 and 102, but are not persuasive regarding the rejection under 35 U.S.C. 103 for reasons discussed below.

2. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., effective at low concentration) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Particularly, claim 2 cites concentration of at least  $10^4$  thrombocytes, which would encompass the concentration disclosed in the prior art. Further, the claim is drawn to composition claims. The optimization of the concentration of an active ingredient in a pharmaceutical composition is considering within the skill of artisan, absent evidence to the contrary.

3. Regarding the remarks that Read teaches away from the claimed invention because Read teaches away from using thrombocyte fragment, it is note again that the limitation are not cited in the rejected claim. Specifically, claim 1 cites "thrombocytes or thrombocyte fragments" which read on composition comprising thrombocytes.

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4. Regarding the remarks about Patat' patent, note that the precipitate containing both platelet (or its fragments) and the thrombin-coagulable proteins. See, particularly, column 2, lines 55-59.
5. Regarding the remarks about the viral inactivation of the platelet composition, note the references teaches that composition made from platelet is known to require viral inactivation, therefore, a thrombocyte composition be free of virus is prima facie obvious.
6. Applicants' remarks that the claimed composition has superior effects compared to the cited prior art, as well as the data presented at page 10-12 in the specification have been fully considered, but are not persuasive.

Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Further, A DECLARATION UNDER 37 CFR 1.1323 must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case of obviousness. See, MPEP 716.02 (e). In example 7, it states the patients therein have been treated by surgical or conservative topical therapies; it is unclear what kind of conservative topical therapies had been used on these patients. Absent evidence to the contrary, one of ordinary skill in the art would reasonably expect that the platelet composition taught by Read and Patat would be similarly useful as those disclosed in examples 1 and 2 in the instant application.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

AU 1617

April 10, 2002

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200